INPLASY

Diagnostic Performance of Hepatitis C Virus Core Antigen for Acute HCV Infection among People with HIV: A Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No financial support.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - C.C. Hung has received research support from Gilead Sciences and speaker honoraria Gilead Sciences and served on advisory boards for Gilead Sciences. H.Y. Sun has received research support from Gilead Sciences. G.J. Chen has received research support from Gilead Sciences. T.Y. Tsai has no competing interest to disclose.

INPLASY registration number: INPLASY202530106

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2025 and was last updated on 24 March 2025.

INTRODUCTION

Review question / Objective Is HCV core antigen (HCVcAg) testing able to be used to test acute or recent infection among people with HIV (PWH)?

Condition being studied People with HIV (PWH) are at a higher risk for repeated hepatitis C virus (HCV) infection. HCV core antigen (HCVcAg) has been validated as an effective diagnostic tool to identify active HCV infection. However, its efficacy in diagnosing acute HCV infection warrants further investigation. This systematic review and meta-analysis aimed to evaluate the diagnostic performance of HCVcAg in detecting acute HCV infection among PWH.

METHODS

Search strategy We will examine PubMed, EMBASE, Scopus, Web of Science (WoS) databases for English-language studies that assessed the diagnostic performance of HCVcAg from January 2000 to May 2024. We will use search terms encompassing HCV, core antigen, HIV, sensitivity, and specificity. We will also review citations from the existing several systematic reviews and meta-analyses evaluating the sensitivity and specificity of HCVcAg in active HCV infection to identify additional eligible studies.

Participant or population People with HIV who used HCVcAg testing to examine acute or recent infection.

Intervention HCVcAg test (Abbott Architect® HCV Ag assay, Abbott, Germany).

Comparator Nucleic Acid Amplification Tests as gold standards.

Study designs to be included Case-control, cross-sectional, cohort or randomized control studies.

Eligibility criteria Inclusion: (1) PWH enrolled either for acute HCV infection testing or with available anti-HCV data to establish acute HCV infection; (2) case-control, cross-sectional, cohort or randomized control studies; (3) using Architect® HCV Ag assay (Abbott, Germany) as the diagnostic tool and NAATs as the reference standard; and (4) available numbers of true positive (TP), false positive (FP), true negative (TN) and false negative (FN), preferably listed as a table.
Exclusion:
(1) lacked any figures of the sensitivity, specificity, TP, FP, TN, or FN; (2) provided insufficient data on timing of HCV infection; (3) aimed to evaluate treatment response of DAAs; (4) utilized antibody or antibody-antigen combined test; or (5) consisted only of conference abstract only with unpublished data.

Information sources PubMed, EMBASE, Scopus, Web of Science (WoS) databases.

Main outcome(s) The sensitivity and specificity of the HCVcAg test.

Quality assessment / Risk of bias analysis We use Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) for quality assessment.

Strategy of data synthesis Statistical analysis will be performed using STATA version 18 (StataCorp, College Station, TX, USA) to calculate the pooled sensitivity, specificity, PLR, and NLR with 95% confidence interval (CI) of HCVcAg, using NAATs as the reference standard. Results will be visualized through forest plots and summary receiver operating characteristic (sROC) curves.

Subgroup analysis No subgroup analysis will be performed.

Sensitivity analysis Sensitivity analyses will be performed to evaluate our results' robustness across each outcome.

Language restriction English.

Country(ies) involved Taiwan.

Keywords Acute hepatitis C, People with HIV, Screening.

Contributions of each author

Author 1 - Tsung-Yu Tsai - TY Tsai independently screens titles and abstracts for eligibility and conducted full-text review for articles selected by either reviewer, and extracts published year, first author, study location, design, number of participants, participant characteristics, clinical settings, reference standards with detection limits, diagnostic performance metrics.
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